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The Impact Self-Monitoring of Blood Glucose (SMBG) on Metabolic Control in Patients with Type 2 Diabetes. A Developing Country Perspective

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Abstract

Introduction: The role of Self-Monitoring of Blood Glucose (SMBG) in patients with type 2 diabetes remains inconclusive. As part of the approach to improve glycaemic control in patients with T2DM in Trinidad a high prevalence setting for T2DM, the Ministry of Heath distributes free glucometers and strips. The aim of this study is to evaluate the impact of SMBG on glycaemic control and to determine patients' behaviors and responses.

Methods: A large outpatient clinic for patients with T2DM was selected for the study. All clients who met the entry were eligible for entry into the study using a systematic sampling technique. A structured pretested questionnaire was administered to all participants to collect all data including the use of a glucometer. HbA1c was measured, to assess glycaemic control. All data was stored, retrieved and analyzed in SPSS vs 16.

Results: 214 participants were recruited for the study. We found a significant difference (p=0.002) in glycaemic control (HbA1c ≤ 7.0%) between users of a glucometer (12, 14%) compared to clients not using a glucometer 42(32.6%) were well controlled.

Conclusion: The study showed no direct benefits of self-monitoring of blood glucose in attaining optimal glycaemic control in patients with T2DM.

Keywords: Self-monitoring of blood glucose, Type 2 Diabetes, Glycaemic control, HbA1c

Introduction

The goal of diabetes treatment is to control blood glucose to prevent the development of or to delay progression of diabetes complications and thus maintain good quality of life. International Clinical practice guidelines recommend self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes or insulin-treated type 2 diabetes [1,2]. However the cost-effectiveness and clinical utility of SMBG in patients with noninsulin-treated type 2 diabetes remain controversial [3,4]. The American Diabetes Association cited several studies, which suggest that SMBG reduces haemoglobin A1c (HbA1c) by only 0.25% at 6 months, and a Cochrane review, which concluded that the overall effect of SMBG in such patients is minimal up to 6 months after initiation and subsides after 12 months [5-9]. A further consideration is that SMBG alone does not lower blood glucose level, therefore to be useful the information must be integrated into clinical and self-management plans. In addition its indiscriminate use can cause a waste of resources and psychological harm [10].

Specifically, Malanda et al. [9], in a review of 12 randomized clinical trials concluded that SMBG for patients with type 2 diabetes mellitus (T2DM) not on insulin had only a minimal, though statistically significant, impact on improving glycemic control in the short term (a reduction in HbA1c of 0.3% after 6 months) and an even more minimal, and non significant, impact on HbA1c in the long term (−0.1% at 12 months). Furthermore, they noted that there was no evidence that introducing SMBG affected changes in patient well-being, quality of life, or satisfaction. These findings are similar to those reported in previous reviews [11-14], which included many of the same studies. These conclusions advance an important issue: if SMBG at the population level is clinically inefficacious, then there is little justification for directing sparse clinical and financial resources to support SMBG. In fact, in response to these findings, health care systems in several countries, including Germany, Sweden, France, and Canada, have already curtailed reimbursement for SMBG among type 2 diabetic adults not on insulin.

On the other hand recent studies utilizing SMBG as an integral component of diabetes care showed improvements in mean glucose [15-19], glycemic variability [15] metabolic risk factors [17], depression and diabetes-related distress [20], and health behaviors. [17-19]. In addition if the goal is to ensure that clinicians have the data needed to propose timely medication adjustments and/or lifestyle recommendations or perhaps to alert patients that dietary or activity changes need to be made then SMBG may provide the data. In fact the use of SMBG, structured in timing and frequency, was associated with changes in clinician behavior, with earlier and more frequent changes in the prescription of diabetes medications [18-21].

Trinidad is a small developing country with a large burden of

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T2DM. In response to this emerging epidemic glucometers are provided to patients as a national health policy. Although structured SMBG is beneficial there is no evidence of its usefulness as an appropriate strategy in this setting. Thus the aim of this study is to evaluate the impact of SMBG on glycemic control and to determine patients' behaviors and responses.

Methods

The study involved a large diabetes outpatient clinic with laboratory support for HbA1c assessment in the Eastern half of Trinidad. All adult patients (>18 years) irrespective of the duration of type 2 diabetes or treatment were eligible. Patients were ineligible if they were on insulin therapy with previous use of structured SMBG, impending complications of diabetes, or limited life expectancy or if they were pregnant, breast feeding, or intended to become pregnant or had type 1 diabetes. We defined T2DM as having a fasting glucose level of 126 mg/dL or higher (≥7.0 mmol/L), a non fasting glucose level of 200 mg/dL or higher (≥11.1 mmol/L), hemoglobin A1c level of 7% or higher, or the use of an oral hypoglycemic agent (OHA) or insulin at the time of consideration for entry into the study. All patients who met these criteria were eligible for entry into the study. We used a systematic sampling technique in which every 10th client was invited to participate in the study, there were no refusals giving a 100% response rate. We choose one facility to avoid varying clinical practices and to control simultaneously for the possible confounding effects of different variables.

We defined the Self-Monitoring of Blood Glucose (SMBG) as the process of pricking a finger with a lancet device to obtain a small blood sample, applying a drop of blood onto a reagent strip, and determining the glucose concentration by inserting the strip into a reflectance photometer for an automated reading. The Ministry of Health supplied all instruments used in the study. This meant all subjects were using the same type of instrument and test strips. Patients recorded their test results either manually using a logbook or it was stored in the meter's electronic memory.

Demographic and clinical data were collected using a structured interview administered questionnaire. After obtaining consent a peripheral venous blood specimen was obtained from each participant via an antecubital vein. HbA1c was measured by an immunoturbidimetric method using an automatic analyzer. All patients were given their results to take to their physician.

Analysis was initially performed based on a series of univariate comparisons and the χ^2 test was used to detect association between patient characteristics and significance was set at p=0.05. Summary statistics and two-sided 95% CIs were computed for mean changes. The Ethics Committee of the University of the West Indies granted ethical approval for the study.

Results

We recruited 214 participants who satisfied the entry criteria. The mean age was 63 years. The majority of participants were in the age group 56-65 years (64, 30%), and there were more females than males (f: m =1.7:1). In Trinidad the two major ethnic groups are Africans and South East Asians (SEA) both representing approximately 35% of the population. SEA was however over represented in the sample, as the ratio of SEA to Africans, was 3.3: 1, table 1. This can be partially explained by two factors- the location of the study has more SEA than Africans living in that community and T2DM is more common in SEA than Africans. Of the 214 participants in the study one patient was receiving lifestyle modifications (diet and physical activity) only for the treatment of T2DM. The majority (164) of participants were on OHA, 44 participants were on OHA and insulin and five participants were using insulin only. We identified 85 (40%) participants who were currently practicing SMBG, which we called the SMBG group. This group was marginally younger mean age of 60 years with 53 females and 32 males (f:m=1.7:1). No participant was currently practicing structured SMBG. The 129 (60%) participants who were not practicing SMBG were called the non-SMBG group.

Table 1: Characteristics of the study sample by age, gender, ethnicity and glucometer use.

Characteristic	n (%)
Age	
30-45	17(7.9)
46-55	44(20.6)
56-65	64(29.9)
66-75	56(26.2)
>76	33(15.4)
Total	214(100)
Gender	
Male	77(36)
Female	137(64)
Total	214 (100)
Ethnicity	
African	45(21)
East Indian	148(69.2)
Other	21(9.8)
Total	214(100)
SMBG	85(40)
Non-SMBG	129(60)
Total SMBG	214(100)
HbA1c ≤ 7 Non-SMBG HbA1c ≤7	12(14) 42(32.6)

The mean age of this group was 63 years and there were 84 females and 45 males (f: m=1.9:1). Using an HbA1c of ≤ 7 as an indicator of adequate control of T2DM, there was a significant difference (p=0.002) between the two groups in regard to attaining an HbA1c of ≤7. Only 12(14%) participants in the SMBG group had attained adequate control. On the other hand of the 129 participants in the non-SMBG group, 42(32.6%) were well controlled.

A significantly higher proportion of participants (p=0.01) in the SMBG group identified a target blood sugar level of 140mg/dL as their required goal of treatment (76, 90.5%) compared to the non-SMBG group (31, 26.9%). However in regard to hypoglycaemia defined as a random blood sugar of ≤50mg/dL only 6 (7.1%) participants overall were able to correctly identify hypoglycaemia. The majority of participants (73.8%) reported that their physician explained the results of their HbA1c test to them. All participants in the SMBG group reported that they felt using the glucometer was helping them to achieve their blood sugar targets and were interested in continuing to use it. Most patients tested themselves (78.8%), however only 26.2% ever made a record whether manual or electronic of the result. Although the timing and frequency of testing varied, many more participants tested before meals (85.9%)than after meals (4.7%) while some participant (9.4%) tested at anytime and the majority tested (92.4%)only once for the day. When the participant thought the result was high 82.4% did nothing while 17.6% responded in several ways:1) increasing their medication, 2) used alternative medications, 3) exercised or 4) drank water. No participant ever attempted to inform their health provider. When the participant considered that their blood sugar was low 96.2% drank a sweetened beverage while 7.1% stopped their medication, again no participant informed their health care provider. The majority of patients (91.8%) found that the instrument was easy to use and had no experiences of anxiety. However, only 73.8% reported that they received previous instructions on how to use the instrument. The majority of participants reported that (91.8%) that the instrument functioned without problems. A support group was set up for all patients however only 4.7% attended.

Discussion

Perhaps the most important result from this research is the significant difference (18.2%, p=0.002, 95%CI 7-28) in the proportion of patients who attained an HbA1 ≤7 in the group using a glucometer (14%) compared to those not using a glucometer (32.6%). This finding albeit from a small developing country setting has provided further evidence that discretionary, unstructured SMBG does not improve the management of T2DM. This is in contrast to intensive,

structured SMBG in which the data is used by clinicians to optimize prescription of diabetes medications and by patients to modify their behaviors. Although self-monitoring is considered the 'cornerstone' of diabetes care [22], and may improve glycaemic control in patients with type 1 diabetes [14], it continues to be of questionable value in type 2 diabetes management [15-17]. The implication of this finding on the current supply of glucometers to patients with T2DM by the Ministry of Health is therefore unsupported by the evidence provided in this study. Further in Trinidad self-monitoring equipment are easily available to patients with type 2 diabetes, and is also marketed as a desirable health-related product. Therefore it is likely that the use of this equipment will increase, despite the clinical efficacy remaining inconclusive. A study by Gomes and colleagues showed that overall use of self-monitoring increased by almost 250% from 1997 to 2008 in Ontario [18]. The study also showed that 60% of patients taking diabetes medications not known to cause hypoglycemia and 30% of patients who did not use any diabetes drugs were dispensed blood glucose test strips [18]. Even in the developed world concern has been articulated about the wholesale provision of monitoring equipment without either a clear rationale for use or education to ensure effectiveness, especially given the cost [13,16,19-21]. Thus SMBG will continue to be a contested issue in diabetes management [22].

The study demonstrated that although a high proportion of participants in the SMBG group (90%) could clearly identify a target blood sugar level knowledge of both hyper- and hypoglycaemia and the appropriate responses were lacking. SMBG requires people with diabetes to be proficient and accurate in both operating a blood glucose meter and interpreting their SMBG results to take action (i.e., Glucose Pattern Management [GPM]). For people with diabetes to maximize their time and monetary investment in SMBG, proficiency and accuracy in performing blood glucose checks and recording results are not enough. The value of SMBG is realized only when they are able to use their SMBG data to manage their diabetes and improve outcomes. This requires the ability to interpret SMBG results.

In regard to timing and frequency of testing, the study found that the majority of participants (92.4%) tested once daily and before meals (85.9%) than after meals (4.7%). Scherbaum and colleagues in a randomized controlled trial showed that one SMBG per week is as sufficient and safe as four SMBG per week to maintain HbA1c in non-insulin treated T2DM close to metabolic target [23]. However a consensus opinion among a group of experts from the UK suggested that patients with T2DM using OHA should monitor their blood glucose at least once daily, varying the time of testing between fasting, preprandial and postprandial levels during the day [24]. A global consensus conference on SMBG recommended eleven measurements a week [25] and in 2006 a consensus conference noted that patents with T2DM on OHA may use SMBG but specific recommendations with respect to frequency were not made [26]. How many blood glucose tests are necessary and how should the frequency and timing of tests be structured? We believe the answer would vary depending on the clinical concern addressed. Is the goal to assure that clinicians have the data needed to propose timely medication adjustments and/or lifestyle recommendations? Or perhaps it is to alert patients that dietary or activity changes need to be made? Whatever are the desired outcomes, a precondition requires that patients must know how to test, why they are testing, what the data mean, and what they can do.

Patients placed a great deal of prominence on owning a meter. In fact every patient in the study felt that the glucometer was helping them to achieve their blood sugar targets and were interested in continuing to use it despite the fact that 86% of these patients had a HbA1 ≥7. Clearly therefore HbA1c may not be the only measure to assess the role of the glucometer in the care of patients with T2DM. In fact the evaluation of SMBG including this study has overwhelmingly relied upon glycosylated haemoglobin as measured by HbA1c as the sole outcome measure to evaluate its success or failure [27-29] Very little research has addressed broader issues, such as quality of life [10,30]. For example the use of blood glucose meters is assumed to give more power to patients by encouraging greater involvement in self-care and, in so doing, generate more equal partnerships between patients and health professionals [31]. Patients' views about self-monitoring are almost entirely absent from current research. We feel that this is an alternative metric for evaluating the value and utility of a "behavior-based" intervention, such as SMBG, because it reflects its true clinical impact.

An important finding of the study was only 4.7% of participants attended a group education program. These finding raises two issues firstly if patients do not attend counseling sessions it will not raise the level of diabetes management education required to interpret and use the results of SMBG and secondly group educational programs have been shown to be more effective than individual counseling. In fact Hwee and colleagues reported that compared with those attending individual counseling, patients who went to group classes were less likely to visit the emergency room, be hospitalized for hypo- or hyperglycemia, or develop foot ulcers/cellulitis [32]. Group-therapy recipients were also more likely to have adequate HbA1c and lipid testing and to receive statins than those getting one-on-one care [32]. In addition it is more efficient in terms of resource utilization [33-41].

The major limitation was our sample size, as it may not have allowed for data saturation. Nevertheless, many of our findings support the existing literature. While the target population consists of two major ethnic groups, our sample was dominated by one ethnic group and therefore not representative of the population, which threatens the external validity of the study. Another limitation was that our study design excluded the assessment of the effect diet and physical exercise.

In conclusion there have been considerable advances in the technology of assessing real-time glucose levels in patients with diabetes. These advances have facilitated the adoption of self-monitoring of blood glucose levels as part of the routine care of diabetes managed with insulin. People with diabetes can obtain a quick and accurate reading of their blood glucose level and use this information to adjust their insulin to reach evidence-based therapeutic targets. In contrast, patients withT2DM are managed with OHA typically cannot adjust their treatment in response to a specific blood glucose reading. Thus, the study showed no direct benefits of self-monitoring to this group of patients. Ultimately what is required are prospective trials that examine under what conditions to make best use of this tool so that a broad, indiscriminate approach can be avoided.

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